UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,863	08/03/2000	Renate Konopitzky	12/211	8920

26111 7590 12/18/2002

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, DC 20005-3934

EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/631,863	KONOPITZKY ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *6-16,18-32 and 35-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,17,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election with traverse of group I, claims 1-5, 17, 33-34, SEQ ID NO:2, species full length sequence in Paper No. 11 is acknowledged. The traversal is on the ground(s) that 1) It would not be a serious burden for the Examiner to search all the groups together, because they are products and processes of use which are related, and should be rejoined if group I is allowable, according to *In re Ochiai*, 2) The classification for different groups are limited and have considerable overlap between the groups, 3) The searches for proteins fragments and derivatives, nucleic acids encoding such proteins fragments and derivatives, and a particular functionality, i.e. inducing an immune response or treating or preventing cancer, all are co-extensive, and would not impose a serious burden for examination together, 4) The searches for full length sequences or fragments thereof are co-extensive, and would not impose a serious burden for examination together. The Examiner has not identified generic claims , and each of the disclosed species to which claims are restricted, and provided reasoning for the restriction of the species, and 5) According to MPEP 803.04, even different from each other, a reasonable number of sequences, normally ten sequences, will be examined in a single application. This is not found persuasive because of the following reasons: 1) The different groups are related as products and processes of use, wherein the scope of the processes is not the same as the scope of the products. Therefore, the searches for different groups are not co-extensive, and it would be a serious burden for the Examiner to examine them all together, 2) Although there is overlap of classification of different groups, the searches for different groups are not co-extensive, because the

searches for different groups are complex, and require different database, and not just based on classification search. 3) Proteins fragments and derivatives, nucleic acids encoding such protein fragments and derivatives are structurally distinct. Further, inducing an immune response or treating or preventing cancer are related to protein fragments or nucleic acids encoding such protein fragments as products and processes, wherein the scope of the processes is different from the scope of the products. Therefore, the searches for protein fragments and derivatives, nucleic acids encoding such protein fragments and derivatives, and a particular functionality, all are not co-extensive, and would impose a serious burden for examination together. 4) It is clear that claim 3 is a generic claim for different species fragments of SEQ ID Nos: 88-102. Further, as clearly stated in previous Office action of paper No:13, page 2, the different species fragments comprise a generic fragment, or any one the specific fragments of SEQ ID Nos: 88-102. In addition, page 2 of said Office action clearly states the reasons for the restriction, i.e., the full length sequence and different fragments are each structurally distinct. Therefore, the searches for the full length sequence and different fragments are not co-extensive, and would impose a serious burden for examination together, and 5) Due to the complex nature of the claimed material, it is proper to restrict the invention to one sequence. See MPEP 803.04. Moreover, since MPEP 803.03 and 803.04 only state that up to 10 independent and distinct sequences will be examined in a single application without restriction, the exact number of sequences to be examined is not required.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-5, 17, 33-34, SEQ ID NO:2 and the generic fragment, i.e. an immunogenic fragment of SEQ ID NO:2, are examined in the instant application.

OBJECTION

O/R withdrawn

1. Claim 33 is objected to because claim 33 is drawn to the same composition as claim 17.

Applicant is advised that should claim 17 be found allowable, claim 33 will be rejected under 35 U.S.C. 101 as being a substantial duplicate thereof, When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP 706.03(k).

2. Claims 33 and 34 are objected to because they depend on non-elected claim 18.

Claim Rejections - 35 USC § 112, SECOND PARAGRAPH

O/R withdrawn

Claims, 3, 5, 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims, 3, 5, 34 is indefinite for the use of the language "derived from" in claims 3 and 34. It is not clear how the fragments are derived from the tumor-associated antigen of SEQ ID NO:2.

Claim Rejections - 35 USC § 101, UTILITY

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-5, 17, 33-34 are rejected under 35 USC 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 1-5, 17, 33-34 are drawn to the tumor associated antigen of SEQ ID NO:2, fragments thereof, and a pharmaceutical composition comprising SEQ ID NO:2 or fragments thereof.

The specification discloses isolation of a polynucleotide of SEQ ID NO:1, which is assumed to encode SEQ ID NO:2 (p.8, lines 16-19). The specification further discloses that SEQ ID NO:1 is overexpressed in kidney cancer as compared to normal kidney (p.7 and figure 2). No disclosure is found in the specification concerning detection of the expression or overexpression of the putative encoded protein of SEQ ID NO:2 in any cancer tissue. The specification also discloses potential MHC-binding peptide fragments from SEQ ID NO:2 (p.29-30). However, no disclosure is found in the specification concerning actual detection of the presentation of these fragments by CTLs in any cancer patients. The specification contemplates making antibodies specific for SEQ ID NO:2 or fragments thereof, induction of an immune response, such as induction of CTLs or antibodies, and treating or preventing cancer (p.5, summary). However, no actual

treatment of any cancer using the claimed SEQ ID NO:2 or fragments thereof is found in the specification.

The contemplated utilities are based on the assumption that SEQ ID NO:2 is expressed or overexpressed in cancer cells. However, there is no teaching of whether any protein product is actually produced, or even if translated, whether the overexpressed RNA leads to overexpressed protein. It is well known in the art that regulation of mRNA translation is one of the major regulatory steps in the control of gene expression (Jansen, M et al, 1995, Pediatric Res, 37 (6): 681-686). Those of skill in the art recognize that expression of mRNA, specific for a tissue type, does not dictate nor predict the translation of such mRNA into a polypeptide. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. For instance, Shantz and Pegg (Int J of Biochem and Cell Biol., 1999, Vol. 31, pp. 107-122) teach that ornithine decarboxylase is highly regulated in the cell at the level of translation and that translation of ornithine decarboxylase mRNA is dependent on the secondary structure of the mRNA and the availability of eIF-4E, which mediates translation initiation. McClean and Hill (Eur J of Cancer, 1993, vol. 29A, pp. 2243-2248) teach that p-glycoprotein can be overexpressed in CHO cells following exposure to radiation, without any concomitant overexpression of the p-glycoprotein mRNA. In addition, Fu et al

(EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Yokota, J et al (Oncogene, 1988,Vol.3, pp. 471-475) teach that the retinoblasma (RB) 115 kD protein is not detected in all nine cases of lung small-cell carcinoma, with either normal or abnormal size mRNA, whereas the RB protein is detected in three of four adenocarcinomas and all three squamous cell carcinomas and one of two large cell carcinomas expressing normal size RB mRNA. Thus, predictability of protein translation or the extent of translation is not solely contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. For the above reasons, one of skill in the art would not be able to predict if SEQ ID NO:1 is translated into a polypeptide expression product, or even if translated, whether it is overexpressed.

Moreover, neither the specification nor any art of record teaches what SEQ ID NO:2 is, what it does do, they do not teach a utility for any of the fragments or the derivatives claimed, do not teach a relationship to any specific diseases or establish any involvement in the etiology of any specific diseases.

In addition, the asserted utilities for SEQ ID NO:2, such as production of and screening of antibodies apply to many unrelated polypeptide structures sequences. Therefore the asserted utilities are not considered specific utilities, i.e. they are not specific to SEQ ID NO:2.

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Claims 3, 34 are drawn to an immunogenic fragment derived from SEQ ID NO:2 and pharmaceutical composition comprising said fragment.

Claims 3, 34 encompasses polypeptides of any length, and any structure, provided said polypeptides share with SEQ ID NO:2 a common fragment, which could be as little as a few amino acids.

Although drawn specifically to the DNA art, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly relevant to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The instant specification fails to provide sufficient descriptive information, such as definitive strutural or functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability

may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus, SEQ ID NO:2 alone is insufficient to describe the claimed polypeptides. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of the claimed polypeptides. Thus, applicant was not in possession of the claimed polypeptides.

Thus, there is insufficient support of claims 3 and 34 as provided by the Interim Written Description Guidelines published in the June 5, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore, only an isolated polypeptide comprising SEQ ID NO: 2, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-5, 17, 33-34 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by a specific and/or well established utility for the reasons set forth in the rejection under 35 USC 101 above, one skilled in the art clearly would not know how to use the claimed invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

If Applicant could overcome the above 101 and 112, first paragraph rejections, claims 4-5, 17, 33-34 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tumor associated antigen of SEQ ID NO:2, does not reasonably provide enablement for the tumor associated antigen of SEQ ID NO:2, or fragments thereof, wherein said tumor associated antigen or fragments thereof induces humoral immune response, or a pharmaceutical composition comprising the the tumor associated antigen of SEQ ID NO:2, or fragments thereof . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 4-5, 17, 33-34 are drawn to the tumor associated antigen of SEQ ID NO:2, or fragments thereof, wherein said tumor associated antigen or fragments thereof induces humoral immune response, and a pharmaceutical composition comprising the the tumor associated antigen of SEQ ID NO:2, or fragments thereof.

The specification discloses isolation of a polynucleotide of SEQ ID NO:1, which is assumed to encode SEQ ID NO:2 (p.8, lines 16-19). The specification further discloses that SEQ ID NO:1 is overexpressed in kidney cancer as compared to normal kidney (p.7 and figure 2). No disclosure is found in the specification concerning detection of the expression or overexpression of the putative encoded protein of SEQ ID NO:2 in any cancer tissue. The specification also discloses potential MHC-binding peptide fragments from SEQ ID NO:2 (p.29-30). However, no disclosure is found in the specification concerning actual detection of the presentation of these fragments by CTLs in any cancer patients. The specification contemplates making antibodies specific for SEQ ID NO:2 or fragments thereof, induction of an immune response, such as induction of CTLs or antibodies, and treating or preventing cancer (p.5, summary). However, no actual treatment of any cancer using the claimed SEQ ID NO:2 or fragments thereof is found in the specification.

It is noted that inherent in a pharmaceutical composition is *in vivo* use thereof.

One cannot extrapolate the teaching of the specification to the claims because it is well known that the art of anticancer drug discovery for cancer therapy is highly unpredictable, for example, Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones

promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed polypeptide or fragments thereof are effective in treating tumors. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed polypeptide and fragments thereof are effective in treating cancers. In addition,

Hartwell et al (Science, 1997, 278:1064-1068) teach that an effective chemotherapeutic must selectively kill tumor cells, that most anticancer drugs have been discovered by serendipity and that the molecular alterations that provide selective tumor cell killing are unknown and that even understanding the detailed molecular mechanism by which a drug acts often provides little insight into why the treated tumor cell dies (para bridging pages 1064-1065) and Jain (cited supra) specifically teaches that systemic treatment typically consists of chemotherapeutic drugs that are toxic to dividing cells (p. 58, col 2, para 2).

The specification provides no exemplification of or guidance on how to use the claimed formulation or antigen for active immunotherapy in humans. The goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease. However, Ezzell (J. NIH Res, 1995, 7:46-49) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". Ask a venture capitalist or the director

of product development at a large pharmaceutical company and you're likely to get the same response." (p 1, para 1).

Furthermore, it is unpredictable that the claimed fragments could induce a humoral immune response in subjects with tumor burdens. Boon (Adv Can Res, 1992, 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerize or at least depress the capability to respond against the tumor (p. 206, para2). Moreover, self-tolerance may eliminate T cells that are capable of recognizing these epitopes with high avidity (Sherman, LA et al, 1998, Critical reviews in Immunol, 18(1-2): 47-54). In addition, Boon teaches even if activated CTLs are significantly increased, the therapeutic success remains unpredictable due to inconsistencies in antigen expression or presentation by tumor cells (p.178, paragraph before last paragraph).

Further, an anti-tumor agent must accomplish several tasks to be effective. It must be delivered into the circulation that supplies the tumor and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time. In addition the target cell must not have a alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The peptide may be inactivated *in vivo* before producing a sufficient effect, for example, by proteolytic degradation, immunological activation or due to an inherently

short half life of the protein and the *in vitro* tests of record do not sufficiently duplicate the conditions which occur *in vivo*. In addition, the peptide may not otherwise reach the targert because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the peptide has no effect, circulation into the target area may be insufficient to carry the peptide and a large enough local concentration may not be established.

In view of the above, it would have been undue experimentation for one of skill in the art to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by US 6184356.

Claim 3 is drawn to an immunogenic protein fragment derived from SEQ ID NO:2.

US 6184356 teaches a sequence, SEQ ID NO:32, which is 100% similar to a fragment of SEQ ID NO:2, from amino acid 48 to 56, as shown by MPSRCH sequence similarity search (MPSRCH search report, 2002, us-09-631-863a-2.oli.rai, page 1).

Which is it similar to one of the predicted peptides that binds MHC.

Given the peptide sequence taught by US 6184356, one of ordinary skill in the art would immediately envision the claimed polypeptide fragment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PHD
PRIMARY EXAMINER

MINH TAM DAVIS

December 9, 2002